

### III. REMARKS

1. Claims 13-16, 18-19, 21, 23-28, 30-33 and 35 are amended.
2. The Examiner objects to claims 17-23 and 28-35 as being in improper form stating that a multiple dependent claim cannot depend from multiple dependent claim. However, there are no multiple dependent claims pending in this application.

In the Preliminary Amendment filed concurrently with the filing of the application on December 4, 2000, all of the multiple dependent claims present in the priority application (WO 99/62580) were changed to single, dependency claims. A copy of the preliminary amendment is enclosed herewith.

Accordingly, claims 17-23 and 28-35 should be treated on the merits and any issuing Office Action should be non-final.

3. Claims 13-16 and 24-27 are not unpatentable over Younes (US 5107830) under 35 U.S.C. 103(a).

The examiner indicates that, in regards to claim 24, Younes discloses a ventilatory having:

- a first input ( $P_{mus}$ ) for receiving a first signal representative of inspiratory effort and which would have an amplitude;
- a second input (Volume feed back see figs 7 & 9 and supporting text) for receiving a second signal representative of volume and which would have a second amplitude;
- means for calculating which is fully capable of calculating a relationship between the first and second signals (pre-programmed electronics 22); and

- a means for increasing or decreasing ventilation assistance depending on whether or not a present calculated value of said relation is higher or lower than a past calculation of the relation by an amount exceeding a given threshold (pre-programmed electronics 22).

Independent claims 13 and 24 have been amended to recite:

- the calculation of the "neuro-ventilatory efficiency representative parameter" in relation to the first and second amplitudes at predetermined intervals; and
- the increase or decrease of the ventilatory assist level depending on whether a present calculated value of "the neuro-ventilatory efficiency representative parameter" is higher or lower than a past calculated value of that neuro-ventilatory efficiency representative parameter by an amount exceeding a given threshold.

These features are not disclosed or suggested by Younes.

*First embodiment of Younes*

Younes describes a first embodiment illustrated in Figures 8-10 and described in the specification between column 15, first line and column 19, line 38.

In this first embodiment as illustrated in Figures 9 and 10 of Younes, the motor 16 responds to the instantaneous difference, after suitable amplification, between a desired output, being the command signal, and the actual output. As seen in Figure 9, the desired output is inputted by line 70 to a summing amplifier 72 to which also is fed a feedback signal by line 74.

To produce a signal that is proportional to the inspired volume, the inspired volume signal is connected to the command signal. The pressure in the piston chamber 24, as measured by the pressure transducer 48, is used as feedback. If the measured pressure in the chamber 24 is different from the one desired as determined by the summing amplifier 72, then an error signal is generated on line 76. The error signal, after suitable amplification by amplifiers 78, 80, then controls the output of a power amplifier 82 to provide a control signal on line 60 to the motor 16.

Once the flow exceeds a minimal level, a square voltage output is generated which activates valve 50, thereby connecting the chamber 24 to the valve 52 and closing the latter. Flow then continues into the patient as long as patient effort plus pressure output by the ventilator unit 10 exceed the elastic recoil of the respiratory system. When patient effort declines at the end of the patient's spontaneous inspiration, inspiratory flow ceases.

Accordingly, the first embodiment of Younes generates pressure, flow and volume signals. These pressure, flow and volume signals are applied to a summing amplifier either as command signal and feedback signal to produce an error signal that is used to drive the motor through a power amplifier. Therefore, the first embodiment of Younes fails to use the signals, that can eventually be considered as inspiratory effort and lung volume signals, to calculate a "neuro-ventilatory efficiency representative parameter" at predetermined intervals and that is subsequently used to increase or decrease the ventilatory assist level depending on whether a present calculated value of the "neuro-ventilatory efficiency representative parameter" is higher

or lower than a past calculated value of that neuro-ventilatory efficiency representative parameter by an amount exceeding a given threshold as is recited by Applicants in claims 13 and 24.

#### *Second embodiment of Younes*

Younes also discloses a second embodiment with reference to Figure 11 and described in the specification from column 19, line 39 to column 21, line 59, that also does disclose or suggest Applicants' invention as recited in claims 13 and 24.

According to this second embodiment, a coil 205 pushes or pulls on the piston 201 in proportion to the magnitude of the drive potential supplied to the coil 205 via a cable 207.

To produce the drive signal, the rate of flow of gas from the chamber 202 to the patient 208 is measured by a flow meter 209 mounted on the inhalation conduit 210 which generates an instantaneous flow signal. This instantaneous flow signal is conditioned through an externally adjustable gain control 212 before being supplied to an input of a summing amplifier 218.

The instantaneous flow signal is also integrated through an integrator 213 to provide a signal corresponding to instantaneous inhaled volume 214. Signal 214 is also conditioned through an externally adjustable gain control 215, and is finally supplied to another input of the summing amplifier 218.

Other inputs 219 to the summing amplifier 218 may include any of a variety of functions. Two preferred functions are a constant voltage, to provide continuous positive airway pressure (CPAP) if desired, and an input designed to cancel out the effect of inhalation tube resistance.

A switch mechanism 220 channels the output of the summing amplifier 218 to the motor 205 during the inhalation phase and the later part of the exhalation phase. The command signal 222 from the summing amplifier 218 is suitably amplified using a power amplifier 223 and power supply 224.

To control the switch mechanism 220, a differential pressure transducer 227 measures the pressure gradient between a point upstream and a point downstream from the one-way valve 204 that directs flow on the inhalation line 210. The downstream point is preferably as close as possible to the patient to enhance the sensitivity of the transducer 227 to flow, while the upstream point may be conveniently located at the chamber 202. The inhalation phase is defined as any time during which the pressure upstream is higher than the pressure at the point nearer the patient. The exhalation phase is when pressure on the patient side of the valve 204 is higher than in the chamber 202.

In the second embodiment of Younes, flow and volume signals are supplied to a summing amplifier to produce a motor drive signal. This drive signal is supplied to the motor through a switch controlled by a differential pressure measurement. Again, there is no teaching of using the above signals, that can eventually be considered as inspiratory effort and lung volume signals, to calculate a "neuro-ventilatory efficiency representative parameter" at predetermined interval and that is subsequently used to increase or decrease the ventilatory assist level depending on whether a present calculated value of the "neuro-ventilatory efficiency representative parameter" is higher or lower than a past calculated value of that neuro-ventilatory efficiency representative parameter by an amount exceeding a given threshold as claimed by Applicants in claims 13 and 24.

To summarize:

1. Younes's system uses an input of inspiratory effort ( $P_{mus}$ ) and volume to obtain a targeted delivery of ventilatory assist. However the gain/amplification factor that determines the translation inspiratory effort and volume is determined by a fixed preset (by the user) value. This means that if the patient's respiratory function weakens the ventilatory assist will not increase. On the contrary, Applicants' system as claimed calculates a neuro-ventilatory efficiency representative parameter, for example a ratio between diaphragm EMG and lung volume, to adjust the gain/amplification of the assist. In the case of weakened respiratory function, the neuro-ventilatory efficiency index will decrease and assist will increase until ratio is restored.
2. Younes's system measures inspiratory effort from flow and volume and fixed measured or estimated values of respiratory mechanics, i.e. the inspiratory effort is predicted via tertiary signals. There are major limitations associated to this technique: a) respiratory mechanics changes continuously within and between breaths, and b) transformation of neural input in the respiratory muscles pressure generation into flow and volume changes with both altered state of disease and changes in lung volume. In other words, Younes's system cannot measure or accurately predict neuro-ventilatory coupling.
3. Younes's system can be considered as an inner control loop where the amount of delivered ventilatory assist is obtained through the delivered volume in proportion to predicted inspiratory effort. On the contrary, Applicants' system can be considered as an outer control loop which controls the ratio between targeted and obtained ventilatory assist. In other

words, Applicants' system could control and adjust the gain/amplitude of Younes's system.

Therefore, claims 13 and 24 are not disclosed or suggested by Younes. Claims 14-16 and 25-27 depend from claims 13 and 24 respectively, and should also be allowable at least in view of the dependencies.

Claims 17-23 and 28-35, being dependent from allowable independent claims, should also be allowable at least in view of the dependencies.

Other than as explicitly set forth above, this reply does not include acquiescence to statements made by the Examiner.

4. The changes to claims 18, 21, 23, 30 and 35 are merely to correct antecedent basis errors or grammatical errors, do not further limit or narrow the scope of these claims and are not made for reasons related to patentability.

For all of the foregoing reasons, it is respectfully submitted that all of the claims now present in the application are clearly novel and patentable over the prior art of record, and are in proper form for allowance. Accordingly, favorable reconsideration and allowance is respectfully requested. Should any unresolved issues remain, the Examiner is invited to call Applicants' attorney at the telephone number indicated below.

A check in the amount of \$920 is enclosed for a three-month extension of time. The Commissioner is hereby authorized to charge payment for any fees associated with this communication or credit any over payment to Deposit Account No. 16-1350.

Respectfully submitted,

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25 SEPTEMBER 2003  
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